DEPARTMENT OF THE ARMY HEADQUARTERS, U.S. ARMY MEDICAL DEPARTMENT ACTIVITY Fort Sill, Oklahoma 73503-6300

MEDDAC Regulation 1 August 2003 No. 210-3

Installations CONDUCT OF PHARMACEUTICAL AND MEDICAL SUPPLY SALES REPRESENTATIVES

- 1. HISTORY. This issue publishes a revision of this publication.
- 2. PURPOSE. To establish policies and procedures for the conduct of pharmaceutical and medical supply sales representatives with regard to detailing and promotion of drugs and other medical products at U.S. Army Medical Department Activity (USA MEDDAC).

3. REFERENCES.

- a. AR 1-100, Gifts and Donations
- b. AR 40-3 Medical, Dental, and Veterinary Care
- c. AR 40-61, Medical Logistics Policies and Procedures
- d. DOD 5500.7-R, Joint Ethics Regulation
- e. AMSUS Code of Ethics for Sustaining Members (Appendix A)
- 4. APPLICABILITY. This regulation applies to all military and civilian personnel assigned to MEDDAC and to all pharmaceutical/medical supply sales representatives when engaged in the promotion of their products at the MEDDAC.

5. RESPONSIBILITIES.

- a. The Pharmacy and Therapeutics (P&T) Committee is responsible for establishing and recommending policies and procedures pertaining to the conduct of sales representatives.
- b. The Chief, Department of Pharmacy, and Chief, Medical Materiel Branch, Logistics Division, are jointly responsible for ensuring that sales representatives are aware of policies specified in this regulation and conduct business accordingly.
- c. MEDDAC staff members are responsible for adhering to the guidance contained in the Joint Ethics Regulation and AR 1-100 Gifts and Donations (Appendix A) with regard to the legality of accepting gratuities from commercial vendors or representatives. Failure to do so may result in UCMJ action.
- 6. GENERAL. The intent of the policies and procedures contained in this regulation is not to discourage the detailing of pharmaceuticals or presentation of medical supplies and equipment. It is to aid MEDDAC staff and supply representatives in maintaining a high level of ethical conduct serving the best interest of MEDDAC. In this regard, repetitious promotion of the same product is discouraged, whereas detailing of newly marketed drugs, supplies and equipment is encouraged.

^{*}This regulation supersedes MEDDAC Regulation 210-3, dated 1 August 2000.

7. REGISTRATION.

- a. All vendors/sales representatives are required to register and receive a visitor's badge by reporting to the Materiel Management Branch, Logistics Division. Registration will be accomplished prior to visiting clinical staff in hospital wards, clinics or administrative work areas.
- b. All members of the MEDDAC staff are required to escort any vendor/sales representative who is not displaying a MEDDAC visitor's badge to the office of the Materiel Management Branch, Logistics Divisions, for proper registration and clearance.

8. APPOINTMENTS.

- a. Visiting pharmaceutical and medical sales representatives are encouraged to schedule appointments with each area they plan to visit. Random access to hospital nursing units and clinics or attempts to make unscheduled contacts with hospital medical staff is discouraged as it negatively impacts on the mission of patient care.
- b. Appointments can be arranged with the area(s) that the representative(s) plan to visit by contacting the respective department, section, or clinic supervisor or a specific individual.

9. PHARMACEUTICAL REPRESENTATIVES.

- a. Registration. Pharmaceutical representatives are required to obtain a visitors badge from the Logistics Division and to check with the Chief, Department of Pharmacy, prior to visiting physicians, nurses or other health care providers.
- b. Pharmaceutical Detailing. Pharmaceutical representatives are required to brief and acquaint the Chief, Department of Pharmacy, with products, particularly new products, that he or she will be detailing to the medical staff. Pharmaceuticals presented or detailed to the medical staff should be limited to new drugs and/or new indications for use that are improvements in drug therapy and be presented for complete education to the Pharmacy and Therapeutics Committee. All pharmaceutical demonstrations, examinations, and evaluations must be coordinated through the Chief, Department of Pharmacy, and the Chief, Materiel Management Branch. The Chief, Materiel Management Branch, will coordinate these Demonstrations, Examination, and Evaluation Requests Form (Appendix C) with the MEDDAC supporting contracting office.
- c. Drug Samples. Distribution or use of drug samples at MEDDAC is not authorized, IAW MR 40-18, Medication Management and per AR 1-100 and AR 40-3, unless requested through the Pharmacy and Therapeutics Committee and approved by the Commander. Drug samples approved for use will be controlled and dispensed by the Department of Pharmacy. Special purchase of non-formulary drugs will be coordinated with the Chief, Department of Pharmacy, and requested on a New Drug Request, DD Form 2081 (Appendix B).
- d. Prohibitive Actions. Pharmaceutical sales representatives are not authorized to provide food or beverages to MEDDAC staff members. Gifts or gratuities will be in strict accordance with applicable government regulations.

10. MEDICAL MATERIEL AND REPRESENTATIVES.

- a. Medical Materiel/Supplies. Medical materiel/supplies includes those items that do not require formal accountability and are normally consumed in use.
- (1) All medical supply demonstrations, examinations and evaluations must be coordinated through the Chief, Materiel Management Branch. Obtaining proper authorization prior to conducting demonstrations, evaluations or examinations will alleviate the risk of personal liability for MEDDAC staff or pecuniary liability of our vendors.

The Chief, Materiel Management Branch, will coordinate these Demonstrations, Examination and Evaluation Requests Form with the MEDDAC supporting contracting office.

- (2) These events will be of limited duration not to exceed 30 days without the Medical Command (MEDCOM) approval.
 - (3) Expenses for the return of the material to the vendor will be borne by the vendor.
 - (4) The government is not responsible for lost, damaged or destroyed property.
- (5) Activities or individuals examining the item(s) assume no obligations to furnish any report to the vendor on the results of the examination.
- (6) Medical materiel and supply sales representatives are not authorized to provide food or beverages to staff members of MEDDAC.
- (7) Staff members accepting gifts or gratuities will do so in strict accordance with applicable laws, governmental regulations and this policy. MEDDAC staff members will not accept food from medical materiel/supply and equipment sales representatives. Failure to follow these guidelines may result in UCMJ action.
- b. MEDICAL AND NON-MEDICAL EQUIPMENT. Medical and non-medical equipment includes items that normally require formal accountability, do not loose functionality and are not consumed by use.
- (1) Examination, demonstrations and evaluations for equipment must be coordinated through the Property Book Officer (PBO) (medical and non-medical, non-expendable type of equipment) and/or the Chief, Information Management Division (Automatic Data Processing Equipment (ADPE) only). It is the staff member's responsibility to coordinate and track this process for the item(s) they wish to examine. The PBO and/or the MSO will coordinate Demonstrations, Examination and Evaluation Requests Form (Appendix C) with the MEDDAC supporting contracting office.
- (2) Procedures for examination, demonstrations and evaluations of equipment are governed under AR 40-61 Medical Logistics Policies and Procedures include:
- (a) All medical equipment examinations, demonstrations and evaluations must be coordinated through the PBO.
 - (b) These events will be of limited duration not to exceed 30 days without the MEDCOM's approval.
 - (c) Expenses for the return of the material/equipment to the vendor will be borne by the vendor.
 - (d) The vendor, at no cost to the government will provide special maintenance.
- (e) Activities or individuals examining the item(s) assume no obligations to furnish any report to the vendor on the results of the examination.
- (f) All equipment undergoing a demonstration or examination must first pass a safety/technical inspection by the Equipment Management Branch prior to delivery to the requesting staff area.
 - (g) Equipment will be delivered, installed and operated at no cost to the government.
 - (h) The Government is not responsible for lost, damaged or destroyed equipment or property.

- 10. CONTINUING MEDICAL EDUCATION SEMINARS. MEDDAC staff may attend no-obligation, vendor sponsored Continuing Medical Equipment (CME) Seminars providing they have received authorization from their supervisors and the Staff Judge Advocate Ethics Counselor. Staff members will not solicit or coerce sponsoring vendors for these gifts or services.
- 11. OBLIGATION OF GOVERNMENT FUNDS. The MSO is the only individual authorized to obligate government funds for purchase of supplies and equipment the Class VIII and SSSC accounts. Sales representatives will not accept orders for supplies and equipment from any personnel other than the MSO. Staff will not obligate government funds. Obligating government funds could result in disciplinary action and/or personal liability.
- 12. NONCOMPLIANCE. Noncompliance with the policies contained in this regulation or professional misconduct on the part of pharmaceutical and medical supply sales representatives may result in loss of detailing privileges and access to Fort Sill MEDDAC or DENTAC.

APPENDIX A CODE OF ETHICS

Sustaining Membership of the Association of Military Surgeons of the United States of America. The Society of the Federal Health Agencies

PREAMBLE

The principles of the code of ethics are intended to aid the Pharmaceutical and Medical Representative in maintaining a high level of ethical considerations of general standards and represent the objectives toward which every Sustaining Member of the Association should strive. These standards constitute a body of principles upon which these Representatives can rely for guidance.

PRINCIPLE: The Pharmaceutical and Medical Representative should:

- * Principle 1: Provide physicians and members of the medical community with accurate and factual information pertinent to the safe and effective use of his/her company's products. He/she does so by communicating complete product information.
- * Principle 2: Strive continually to improve his/her medical knowledge relative to effective discharges of his/her professional responsibilities.
- * Principle 3: Strive to apply his/her knowledge to fit the specialized needs of Federal Government medical facilities.
- * Principal 4: Conduct his/her activities recognizing that the patient is the primary responsibility of medical personnel.
- * Principle 5: Contact the Commanding Office, Administrator, Pharmacy Officer or designated representative to determine the policy governing his activities within the medical facility and conduct himself/herself in conformance therewith.
- * Principle 6: Apprise the Pharmacy Officer or other appropriate personnel of his/her presence and intended activities on each visit to the medical facility.

The Code of Ethics embodies our desire to uphold the dignity of our profession and accept its self-imposed disciplines.

Reprints of this code available from AMSUS.

APPENDIX B New Drug Request

NEW DRUG REQUEST						
THRU: (Specify Department) Chief	TO: Chief Pharmacy Service	FROM: (Physician's Name and Location)				
1. GENERIC NAME	2. TRADE NAME(S)	3. MANUFACTURER	4. DOSAGE FORM(S)	5. MONTHLY US- AGE (Estimated)		
6. RECOMMENDATIONS ONE TIME PURCHASE GENERAL USE CLINICAL TRIAL RESTRICTIONS (Specify)		7. THERAPEUTIC INDICATIONS				
8. ADVANTAGES OF REQUESTED DRUG		9. DELETED DRUGS (If new drug is approved)				
DATE	TYPED NAME OF REQUESTING PHY		SIGNATURE			
	FOR COMPLETION BY CHIEF OF DEPARTMENT					
10. RECOMMENDATIONS		11. REMARKS				
ONE TIME PURCHAS	SE GENERAL USE					
RESTRICTION	S (Specify in Item 11)					
☐ CLINICAL TRIAL	☐ DISAPPROVED					
DATE	TYPED NAME AND TITLE		SIGNATURE			
FOR COMPLETION BY CHIEF, PHARMACY SERVICE						
12. REMARKS/RECOMMEN	DATIONS					
13. COST COMPARISON						
FOR COMPLETION BY THERAPEUTIC AGENTS BOARD						
14. RECOMMENDATIONS						
□ ONE TIME PURCHASE ONLY □ GENERAL USE □ CLINICAL TRIAL □ STANDARDIZATION □ RESTRICTIONS (Specify in Item 15) □ DISAPPROVED (Specify in Item 15)						
15. REMARKS						
DATE	TYPED NAME AND TITLE		SIGNATURE			

DD FORM 2081, JUL 77

REPLACES DA FORM 4181, 1 NOV 73, WHICH WILL BE USED.

USAPPC V2.00

APPENDIX C VENDOR DEMONSTRATIONS, EVALUATION AND EXAMINATION REQUEST FORM

Vendor Demonstration/Product Display/No Obligation Service Agreement

DESCRIBE the demonstration, evaluation, examination, and product display or no-obligation service:					
DATES, TIME, DURATION AND AREA OR LOCATION of this action:					
STAFF MEMBER/OFFICER IN CHARGE/NONCOMMISSIONED OFFICER IN CHARGE:					

THE PARTIES TO THIS DOCUMENT AGREE AS FOLLOWS:

- 1. Vendor demonstrations, evaluations, examinations, product displays and no-obligation services are conducted for the sole purpose of demonstrating the capability of particular items or services and not for fulfilling mission requirements for an interim time frame. The examination and demonstration of items or services will in no way, expressed or implied, obligate the U.S. Army to purchase, rent, or otherwise acquire the items demonstrated, displayed, or furnished. Normally, vendors will have sole responsibility for furnishing all supplies, equipment, etc., necessary to accomplish the demonstration, display, or service. On occasion, it may be desirable to furnish certain supplies and/or equipment from Government assets to support vendor demonstrations. These supplies and/or equipment will not be furnished unless approved by proper Army authority. The vendor agrees to repair, replace, or fully reimburse the Government for any damage or loss incurred while these supplies and/or equipment are in his/her possession or use. Manufacture, transportation, maintenance, and demonstration of items shall be accomplished without cost to the Army. An authorized representative of the vendor furnishing the item(s) or service(s) shall conduct demonstration(s). Army personnel will neither demonstrate nor endorse the vendor's product(s). The Army assumes no cost or obligation, expressed or implied, for damage to, destruction of, or loss of such equipment, or for damages or injuries resulting from the submission to the Army of defective items for demonstration. The Contracting Officer is the duly authorized representative of the Government for purposes of this agreement.
- 2. The vendor understands that any data provided by the vendor becomes the property of the United States Army and the vendor does not possess a proprietary interest in any of the data provided.
- 3. The vendor will not file any claim against the Army or otherwise seek compensation for any equipment, materials, supplies, information, or services provided.
- 4. The United States Army and the Department of Defense (DOD) are not bound, or obligated to follow any

recommendations of the vendor. The United States Government is not bound, nor is it obligated, in any way to give any special consideration to the vendor on future contracts.

5. In the event the Army agrees to provide any government-owned supplies for use by the contractor, the following statement becomes part of this agreement:

"GOVERNMENT - FURNISHED PROPERTY"

- a. The government will deliver to the vendor, for use only in connection with this agreement, the property described below (hereinafter referred to as "Government-Furnished Property").
- b. Title to Government-Furnished Property shall remain with the Government. The vendor shall maintain adequate control of Government-Furnished Property in accordance with good business practices.
- c. Unless otherwise provided in this agreement, the vendor, upon delivery of any Government-Furnished Property, assumes the risk of, and shall be responsible for, any loss thereof or damage thereto any Government property consumed in the performance of this agreement is reimbursable to the Government.

d. Description (Include nomenclature, model, catalog, and serial number(s), as applicable):	
e. Current Market Value: \$	
VENDOR: (Type or Print Name of Vendor)	
BY: (Vendor Signature)	
(Type or Print Name and Title of Vendor Representative)	(Date)
THE UNITED STATES OF AMERICA	
BY: (Contracting Officer Signature)	
(Type or Print Name of Contracting Officer)	(Date)

MCUA-PH

The proponent of this regulation is the Department of Pharmacy and Logistics Division. Users are invited to submit comments and/or suggestions to Reynolds Army Community Hospital, CDR USAMEDDAC, ATTN: MCUA-PH, Fort Sill Oklahoma 73503-6300.

FOR THE COMMANDER:

OFFICIAL:

SCOTT W. CHILDERS LTC, MS Deputy Commander for Administration

CYNTHIA A. JONES Administrative Officer

Signature Authenticated by Approvert, Approved by Synthia (*1800es. – on:8/25/2003 at 2:05.11 PM

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